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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/831,846 | 08/21/2001 | Shin-Ichi Funahashi | 14875-081001/C2-010PCT-US | 9799 |

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EXAMINER

GUCKER, STEPHEN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/06/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|---|
| Application No. <u>09/831,846</u> | Applicant(s) <u>Furukashi et al.</u> |
| Examiner <u>Stephen Buckner</u> | Group Art Unit <u>1647</u> |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 5/21/03
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-11 is/are pending in the application.
- Of the above claim(s) 1-3 & 5-9 is/are withdrawn from consideration.
- Claim(s) 10 is/are allowed.
- Claim(s) 4 & 11 is/are rejected.
- Claim(s) is/are objected to.
- Claim(s) are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All Some* None of the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: ENGLISH TRANSLATIONS

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- Notice of Reference(s) Cited, PTO-892
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Interview Summary, PTO-413
- Notice of Informal Patent Application, PTO-152
- Other _____

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Part III DETAILED ACTION

1. Applicant's election without traverse of Group II, claims 4 and 10-11, in Paper No. 9, filed 5/21/03, is acknowledged.

2. Claims 1-3 and 5-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for any variant or functional equivalent of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not adequately describe or provide guidance for any and all variants or functional equivalents of SEQ ID NO:2 because no specific biological function is disclosed in the specification for SEQ ID NO:2, other than the instant protein might bind PDZ protein based on just 3 amino acid residues found in the carboxyl terminal of SEQ ID NO:2 and that the instant protein binds another protein of unknown function called "149Y2H#151". The unpredictability in the molecular biological

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protein art is high, and therefore the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved (*In re Fisher*, 166 USPQ 18). The disclosure only has a single example of a protein having the sequence of SEQ ID NO:2, and at this stage, the instant protein is only enabled as a marker for lung cancer as shown by its selective expression in A549 cells and not normal lung tissue (page 31 and Figure 1). All other uses for the protein are not enabled because the disclosure does not teach what ligands bind to the protein extracellularly in order to demonstrate its biological significance or function. Likewise, no working example is provided for the speculative assertion that the protein binds to PDZ protein intracellularly, or indeed, given the fact that the instant protein is an "orphan receptor" lacking any known ligand binding partners, what ligand could be used to induce the binding of PDZ protein to the instant protein. Given the lack of biological function demonstrated for the instant protein, its only enabled use is that of a lung cancer marker. A cancer marker does not have an enabled use beyond the protein itself because the marker's only use is to differentiate between normal lung tissue and oncologies of the A549 type. A marker exists as a particular species of protein. A genus of proteins expanded in scope around a particular marker is not enabled because the marker's only enabled use is to differentiate between normal lung and cancerous lung, absent evidence that variants of the instant protein also are present in lung cancer tissue.

The specification is not enabled for protein variants comprising additions, deletions, or substitutions of amino acids because the functional equivalents of which amino acids can be changed from SEQ ID NO:2 and still retain biological functioning are not taught in the instant

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specification, other than the 3 amino acid residues identified in SEQ ID NO:2 that may allow PDZ binding.

5. Claims 4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is vague and indefinite for not reciting specific hybridizing condition language in the body of the claim, as the metes and bounds of the claim will be different with every hybridization performed at a different temperature, ionic strength, etc. Because SEQ ID NO:2 is an orphan receptor with no disclosed binding ligand and with no teaching as to how to activate the receptor to produce binding to PDZ protein, the term "functionally equivalent" is vague and unclear because the function of the instant protein is unknown in terms of what kind of a receptor it is (usually named after what ligand it binds, e.g. EGF receptor) or what biological function it participates in in terms of normal functioning or disease processes. For example, the instant protein cannot be classified functionally as a tyrosine kinase or an oncogene because no specific functionality as to second messenger system has been identified with the instant protein, and no overall biological function (stimulation of mitosis, etc.) can be shown to be associated with the activation of the instant protein.

6. Claim 10 is in condition for allowance.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

August 11, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600